## Is a low-calorie diet (LCD) key to treating type 2 diabetes holistically? LOUISA ELLS

### Introduction

The NHS England Low Calorie Diet (now called the NHS Type 2 Diabetes Path to Remission programme), is a one-year programme that uses total diet replacement (TDR) and behaviour change support to help achieve weight loss, improve glycaemic parameters and reduce diabetes-related medication in patients living with type 2 diabetes (T2DM, diagnosed within six years of intervention) and excess weight (body mass index [BMI]>27 kg/m<sup>2</sup> adjusted to 25 kg/m<sup>2</sup> for patients of Black, Asian or other minority ethnic backgrounds).1 It was introduced as a pilot programme across 10 Integrated Care Board (ICB) areas in September 2020, and to a further 11 ICBs in January 2022. This was in response to a pledge within the NHS Long Term Plan to test an NHS low-calorie diet programme for people living with obesity and T2DM,<sup>2</sup> based on the evidence of effectiveness reported in the DiRECT study.3

The Re:Mission study was an NIHRfunded evaluation of the NHS Low Calorie Diet pilot that took a mixedmethod, realist-informed approach to deliver a coproduced, comprehensive qualitative and economic evaluation of the pilot. These findings were then integrated with the NHS quantitative clinical analyses,<sup>4</sup> to provide an enhanced understanding of the long-term costeffectiveness of the programme, and its implementation, equity and transferability across broad and diverse populations.

NHS England's analysis of the first 7,540 patients referred to the programme found that 58% of those referred to the programme started it.4 Although more people from deprived areas were referred, it was people from more affluent areas, of younger age and with a longer T2DM diagnosis who were more likely to start the programme. Men, older adults, those with a lower starting BMI or of Asian, Black or other ethnicities were less likely to start. These findings may be explained by some of the Re:Mission study survey insights,<sup>5</sup> which demonstrated that whilst people were motivated to be referred in order to improve their diabetes, weight and health, some inconsistencies in referrer knowledge were identified.

Of those who started the programme 84% completed the 12-week TDR phase, 79% completed the following 4-6 week food reintroduction phase, and just over half (55%) completed the entire one-year programme.<sup>4</sup> Completion rates were lower in those who were younger, least affluent or living with severe obesity. Of those who completed the programme around a third (32%) achieved T2DM remission, which was related to greater weight loss and lower starting HbA<sub>1c</sub>. However, overall the proportion of weight loss was lower for Asian, Black and mixed ethnicity patients.

Whilst more work is required to understand the socio-demographic differences in uptake and impact of the programme fully, our evaluation highlighted the importance of cultural tailoring and competency,<sup>6</sup> and the role of family and peer support.<sup>7</sup> We also identified a number of aspects that may help improve programme engagement and success, that were reported in a mini edition of the British Journal of Diabetes in April 2024.7 These included: having a greater range of TDR products and advice on the use of non-starchy vegetables during TDR; the importance of one-to-one person-centred support; providing additional support with mental health challenges, and managing the programme around busy lives, family commitments and celebrations that revolve around food; providing additional support to service users experiencing emotional and or disordered eating; and ensuring that appropriate support is in place for service users to manage life after programme completion. These findings have informed the development of the national service specification for the programme which has now been rolled out across the England.<sup>8</sup>

Although the Re:Mission study evaluation and NHS clinical data analysis have demonstrated that the programme can work for some people living with excess weight and T2DM, several questions remain. These are: 1) what is the clinical and equity impact of the revised NHS Type 2 Diabetes Path to Remission Programme, which addresses the findings from the evaluation?; 2) what happens to service users after they finish the programme, are the changes made sustainable, and how will this inform the long-term clinical, equity and cost impact of the programme?; 3) why are completion rates poorer amongst younger patients (18-39 years), those from the most deprived areas, those with a higher (40+) starting BMI, and what can be done to address this?; 4) why does lower weight loss occur in Asian, Black and mixed ethnicity patients? 5) what is the impact of the programme on muscle mass and inflammatory pathways?; and 6) what is the impact of the programme on the gut microbiome, given that most TDR products are ultra-processed? Therefore, can we say the LCD programme is a holistic treatment programme that is key to treating T2DM?

# Is a LCD programme a holistic treatment?

Before this question is answered it is perhaps important to reflect on what is meant by holistic care, which has been described as an in-depth understanding of the patient, providing support that addresses their varying physical, emotional, social and spiritual needs.<sup>9</sup> So, whilst the programme advocates a person-centred approach that addresses diet, activity and behaviour change, our evaluation findings highlight the challenges of delivering a truly holistic approach, where more support is required to address the varying emotional, social and spiritual needs across the broad and diverse populations of service users. There also remain several unknowns regarding the physical impacts of the programme. This is particularly important when considering the role of inflammation and the gut microbiome, which has been shown to have a role in the pathogenesis of obesity,<sup>10</sup> and could potentially underpin some ethnic variation,<sup>11</sup> yet little is known about the impact of total diet replacement.<sup>12</sup>

# Is the LCD programme the key to treating T2DM?

Our conclusion is yes and no. Undoubtedly for some people this is a very successful approach to supporting weight loss and improved glycaemic control. However, it is clear that there are some people for whom this programme does not work. This is not surprising given that the programme is reliant upon effective dietary management and weight loss. These are notoriously complex,<sup>13,14</sup> with multiple interacting underlying biological, social, cultural, psychological and environmental drivers, many of which are completely beyond individual control. It is therefore critical that we understand further who may benefit most from this approach, to ensure that appropriate and effective treatment pathways are available for those who may be least likely to benefit. There is also a question outstanding regarding the long-term sustainability of the programme outcomes. Although the DIRECT trial demonstrated that 36% and 7% of LCD participants achieved remission at two and five years respectively,15,16 the population was small, quite homogeneous, and received ongoing monthly support after completing the one-year programme. It is therefore imperative to better understand the longterm sustainability of the approach when delivered to a broad and diverse realworld population, with no or variable structured follow-up support after programme completion.

### Conclusion

Since there is unlikely to be a magic bullet to treat complex diseases like T2DM and

obesity effectively over the long term, we need to continue to build our toolbox of different approaches that can be tailored to meet the needs of different population groups. This person-centred approach is an important part of providing holistic health care, and addressing disparities, where everyone in need receives effective and appropriate support tailored their individual needs to and circumstances. Further research to understand the underlying mechanisms and lived experience differences of LCD approaches across trial and real-world settings remains imperative.

© 2024. This work is openly licensed via CC BY 4.0.

This license enables reusers to distribute, remix, adapt, and build upon the material in any medium or format, so long as attribution is given to the creator. The license allows for commercial use. CC BY includes the following elements: BY – credit must be given to the creator.

**Copyright ownership** The author(s) retain copyright.

**Conflict of interest** LE receives funding from the NIHR, MRC, and Oliver Bird foundation. She is a member of the Association for the study of obesity, Fellow of the royal society for public health, and unpaid member of the ACTION Teens authorship group.

**Funding** The project was funded by the National Institute for Health Research, Health Services and Delivery Research [NIHR 132075]. The views expressed in this paper are those of the author and not of the NIHR or DHSC.

**Study ethical declarations** Ethical approvals for this study were sought from: Leeds Beckett University LREC; Health Research Authority approval IRAS project ID 294667; and the University of York Department of Health Sciences Research and Ethics committee.

#### References

- NHS. NHS Type 2 Diabetes Path to Remission Programme, 2024. Available from: https://www.england.nhs.uk/ diabetes/treatment-care/diabetesremission/
- NHS. NHS long term plan obesity, 2019. Available from longtermplan.nhs.uk/ online-version/chapter-2
- Lean MEJ, Leslie WS, Barnes AC, et al. Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, clusterrandomised trial. Lancet 2018;391(10120): 541-51. https://doi.org/ 10.1016/S0140-6736(17)33102-1
- Valabhji J, Gorton T, Barron E, *et al.* Early findings from the NHS Type 2 Diabetes Path to Remission Programme:

a prospective evaluation of real-world implementation. *Lancet Diabetes Endocrinol* 2024;**12**(9):653-63. https://doi.org/10.1016/S2213-8587(24) 00194-3

- Radley D, Drew KJ, Homer C, *et al.* Participant experiences during the NHS Low Calorie Diet Programme pilot. Findings from an online survey. *Br J Diabetes* 2024;24:1-19. https://doi.org/ 10.15277/bjd.2024.431
- Dhir P, Maynard M, Drew KJ, et al. South Asian individuals' experiences on the NHS low-calorie diet programme: a qualitative study in community settings in England. BMJ Open 2023;13(12): e079939. https://doi.org/10.1136/ bmjopen-2023-079939
- Online First: Qualitative learning from an evaluation of the NHS Low Calorie Diet Programme, 2024 [Available from: https://bjd-abcd.com/index.php/ bjd/issue/view/51.
- NHS. National Service Specification No. 2: NHS Low Calorie Diet Programme, 2024. Available from: NHS England » NHS Type 2 Diabetes Path to Remission Programme service specification (2023)].
- 9. Jasemi M, Valizadeh L, Zamanzadeh V, Keogh B. A concept analysis of holistic

care by hybrid model. *Indian J Palliat Care* 2017;**23**(1):71-80. https://doi.org/10.4103/0973-1075.19760

- Bouter KE, van Raalte DH, Groen AK, et al. Role of the gut microbiome in the pathogenesis of obesity and obesityrelated metabolic dysfunction. *Gastroenterology* 2017;**152**(7):1671-8. https://doi.org/10.1053/j.gastro.2016.12.048
- Balvers M, de Goffan M, van Riel N, et al. Ethnic variations in metabolic syndrome components and their associations with the gut microbiota: the HELIUS study. *Genome Medicine* 2024;**16**(1):41. https://doi.org/10.1186/s13073-024-01295-7
- Montenegro J, Oliveira CLP, Armet AM, et al. Impact of a powdered meal replacement on metabolism and gut microbiota (PREMIUM) in individuals with excessive body weight: a study protocol for a randomised controlled trial. BMJ Open 2023;13(9):e070027. https://doi.org/10.1136/bmjopen-2022-070027
- Forouhi NG. Embracing complexity: making sense of diet, nutrition, obesity and type 2 diabetes. *Diabetologia* 2023; 66(5):786-99. https://doi.org/10.1007/ s00125-023-05873-7
- 14. Frood S, Johnson LM, Matteson CL, Finegood D. Obesity, complexity, and

the role of the health system. *Curr Obes Rep* 2013;**2**(4):320-26. https://doi.org/ 10.1007/s13679-013-0072-9

- Lean MEJ, Leslie WS, Barnes AC, et al. Durability of a primary care-led weightmanagement intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. Lancet Diabetes Endocrinol 2019; 7(5):344-55. https://doi.org/ 10.1016/s2213-8587(19)30068-3
- Lean MEJ, Leslie WS, Barnes AC, et al. 5-year follow-up of the randomised Diabetes Remission Clinical Trial (DiRECT) of continued support for weight loss maintenance in the UK: an extension study. Lancet Diabetes Endocrinol 2024;**12**(4):233-46. https://doi.org/10.1016/S2213-8587(23)00385-6

#### Address for correspondence: Professor Louisa Ells

Obesity Institute, Leeds Beckett University, Leeds, LS1 3HE, UK E-mail: L.Ells@leedsbeckett.ac.uk

Br J Diabetes 2024;**24**(2):177-179 https://doi.org/10.15277/bjd.2024.465